18 Procedures for the Ethical Evaluation of Research Proposals: Proposed Standards

Das EFPA-Standing Committee on Scientific Affairs hat unter Federführung von Edward Van Rossen (Lessius University College) und Nigel Foreman (Middlesex University) und Mitwirkung von Christoph Steinebach Richtlinien für eine berufsethische Evaluation von Forschungsanträgen erarbeitet. Diese sind zu finden auf der EFPA-Website http://science.efpa.eu/information-/proposed-standards-for-research-ethics-evaluation-procedures/. Anregungen und Kommentare sind herzlich willkommen.

Preamble

The following principles are to be regarded as draft recommendations of standards relating to good practices in terms of procedures for the ethical evaluation of proposals for experimental work involving human subjects as participants.

The purposes of these principles are to

(a) avoid undue harm to participants
(b) enhance and improve data gathering and research generally
(c) enhance the profile of psychology as a discipline
(d) enhance chances on publication of data5[1]
(e) avoid litigation against experimenters

The main purpose of posting these draft recommendations on the EFPA website is to get feedback on them. Feedback is welcomed from both experienced and inexperienced stakeholders: from established committees to institutions without any established procedures. Feedback may take the form of comments but also questions. This is a work in progress, and any contribution to it is most welcome.
The committee recognises that there are many ways in which research proposals can be evaluated on their ethical merits and shortcomings. These practices may vary widely across countries and even individual institutions, for example according to whether regulations are prescribed by national competent authorities or individual academic institutions.
However it is hoped that this initiative will result in a set of standards that is shared across Europe, much like the EFPA Meta-Code on Ethics has become a shared set of principles for most if not all European ethics codes of practice.

In such a situation, all EFPA Member Associations should strive for

(a) the establishment of ethics committees suited to fulfil the role described herein

(b) a proper degree of consent with these principles in all (internal and external) regulations and procedures affecting these committees

(c) awareness of and respect for these committees and principles, particularly amongst psychologists involved in experimental work

In the mean time, these draft recommendations may already serve to inspire and support individuals and institutions aiming to improve their procedures and/or research.
If there is an interest for it, EFPA may also create a European platform for stakeholders to discuss particular issues, share their knowledge and experience, and possibly even set up international projects.

Baseline principle and scope

1. Within the science and profession of psychology, no experimental work that involves human subjects other than the researchers themselves, may be conducted without prior ethical approval as described in these principles.

2. Experimental work means any experimental research or any deviation from the usual way of working that is induced by research motives.
3. Experimental research means any type of research with an intervention.
4. Approval should be sought for all work, including that by practicing psychologists, students, etc.
5. Work that is entirely non-controversial and raises no significant ethical issues may be given approval via a fast-track procedure with a “light touch” review. This principle may well be worked out in more detail, to avoid the review system being too bureaucratic and hindering good research rather than stimulating the improvement of research. Special attention may need to be given to particularly challenging fields such as work & organisational psychology. The number of research proposals that require a full ethical review may also be limited by approving a number of more general research protocols that cover certain commonly used research procedures.
6. Experimental work in the frame of undergraduate training may be covered by a single blanket approval to the responsible staff member under the conditions that (a) this is preceded by an ethical review of the training assignment documents by the ethics committee, (b) these students have previously completed ethics approval forms as part of their training, and (c) a summary of the students’ plans are reviewed by a staff member.
7. Any significant departure from a previously approved protocol requires the seeking of new ethical approval.

Ethics committees

8. Ethics committees should be installed under the auspices of either the Member Association itself, or a university department or faculty of psychology, or in some form of collaboration with or between several of these.
9. An ethics committee should consist of at least one chair and two other members.
10. At least two members should be psychologists.
11. When a submitted proposal concerns work by a member of the committee, this member should be kept outside the review and decision making process related to this submission. Obviously the respective member does retain all the rights due to an applicant.
12. Where a submission falls outside the expertise of the members of the ethics committee, outside advice should be sought. When doing so, proper regard should be given to matters of neutrality and anonimisation.
13. These committees should be able to operate in such a way that they can take their decisions autonomously, without outside interference. The only exceptions to this principle occur (a) when outside advice is requested by the committee itself, and (b) when a hierarchically and ethically outranking authority (e.g., a governmental ethical body) dictates other general principles.
14. All psychologists should have a route whereby they can obtain approval of an ethics committee. However, it may be wise to set up a system to prevent rejected applications from being submitted elsewhere without a notification of the earlier rejection to the newly addressed committee.
15. Experimental work executed within (or under the authority or auspices of) an institution harbouring its own ethics committee, may not be conducted in that institution unless this institution’s ethics committee has granted its approval of the proposal. However, this does not necessarily imply that in case of research executed in multiple institutions, multiple committees need to undertake a full ethical review: one or more committees may also decide to defer to another committee’s evaluation or to conduct a collaborative evaluation.

Submission of proposals

16. Ethical approval must be granted before the actual start of the experimental work.
17. Ethical approval cannot be obtained retrospectively.

18. Ethical submission should involve the completion of an ethical approval form (of the kind appended to this document), though this may be tailored to the needs of particular countries, for instance according to the specific ethical code adopted.

19. Any proposal should at least provide details of its aims, the experimental design and specific intervention to be used, the risks involved and the preventive measures taken, the method to be used to recruit participants and obtain informed consent, and the debriefing and follow-up arrangements.

20. A procedure should be specified for the exchange of information not contained in the approval form: questions asked and answers given by the ethics committee or the applicants, spontaneously offered background information, etc.

Evaluation criteria

21. A proposal should be evaluated on, at least, all aspects covered in the approval form. An ethics committee may freely and without prior notice decide to also include other aspects as evaluation criteria.

22. The assessment of research quality is not required as part of ethical scrutiny, although since it is unethical to waste participants' time, it would be expected that any serious flaw detected in the experimental design or protocol would be pointed out to the experimenter by ethical scrutinisers.

23. Particular and careful consideration should be given to experimental work involving participants who are (a) below the age of 18 years, (b) paid or otherwise compensated for their participation, (c) detained (e.g., in prison), (d) disadvantaged physically (e.g., having a significant medical condition), (e) disadvantaged mentally (e.g., having learning difficulties), etc.

24. Particular and careful consideration should be given to experimental work for which a written informed consent may not be obtainable from all participants themselves, but only from a carer or guardian (e.g., because of medical conditions) or not at all (e.g., in real-life social psychology research).

25. Particular and careful consideration should be given to experimental work where an experimental procedure could be deemed deceptive, produce discomfort, or imply a risk for the participants, research staff or society at large. In this context, "discomfort" and "risk" can be emotional, situational or physical, and need not necessarily be entirely rational.

26. Participants should be provided with an opportunity to discuss with the psychologists involved any aspect (and particularly negative misconceptions) of the experimental work in which they participate or have participated, both during their participation and for a reasonable period of time after their participation is completed.

27. Participants must be made aware that they can withdraw at any time without any penalty, and can demand that their data be removed from the study.

28. Participants must be given information that enables them to easily contact the ethics committee or another appropriate authority in case they have any questions or complaints.

29. A route should always be specified whereby participants can, following participation, obtain support from the experimenter in the event of their experiencing any negative consequences. As a minimum, a follow-up e-mail contact address and phone number should be provided.

30. Any work conducted should be the subject of a detailed risk analysis for experimenters and their co-operators as well as participants and society at large. Protective and preventive measures (including information and insurance) should be offered insofar as this seems indicated by this risk analysis.

Decision making and approval

31. The evaluation procedure should be subject to maximum time-laps between the submission of a correctly filled-out approval form and the related positive or negative conclusion of the ethics committee. A clock-stop may be introduced to allow applicants time for answering questions and submitting additional information.

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32. A decision to approve a proposal should be taken by a majority of votes of at least half plus one members in favour. Failure to reach such a majority means that a proposal must be rejected.

33. Approval of a proposal may be communicated to the applicant as subject to very specific conditions (e.g., "Your proposal is approved on the condition that you demonstrate having a good insurance to cover risk X.")

34. Approval should be time-limited (e.g., to 3 years from the date of obtaining the original approval).

Fees

35. An ethics committee may require modest fees to be paid for its services. Such fees may differentiate between different types of applicants (e.g., students, staff members, associates, outsiders, multiple institutions) and proposals (e.g., proposal with or without potential or likely risk for participants). Any differentiation in fees should be properly motivated to the candidates.

Adverse events and disciplinary measures

36. The ethics committee must be notified as soon as possible of any significant adverse event occurring during or immediately after the experimental work – even if the link between the experimental work and this event is still unclear. The ethics committee shall subsequently notify all appropriate authorities.

37. The ethics committee must be notified as soon as possible of any significant adverse event that has a demonstrated or presumed link with the experimental work – even if this event didn't occur during or immediately after the experimental work and regardless of who claims that there is such a link. The ethics committee shall subsequently notify all appropriate authorities.

38. Where an experimenter fails or failed to adhere to these principles (e.g., begins data collection before ethical approval has been granted), to the approved proposal (e.g., a significantly different intervention) or to basic professional or scientific principles (e.g., by fabricating data or misrepresentation of data), appropriate corrective and disciplinary procedures should be applied.

Additional Recommended Resources

- British Psychological Society (BPS) Guidelines for minimum standards of ethical approval in psychological research (including a template for an ethical approval form), Ethical principles for conducting research with human participants, and other such documents: via www.bps.org.uk/the-society/code-of-conduct/support-for-researchers_home.cfm
- Framework for Research Ethics of the (UK) Economic & Social Research Council: via www.esrc.ac.uk/about-esrc/information/research-ethics.aspx
- Guidelines & recommendations for ethics committees by the European Forum for Good Clinical Practice (EFGCP): via www.efgcp.be
- WHO Scientific and Ethical Review Group Guidelines for the establishment of scientific and ethical review bodies: www.who.int/reproductivehealth/topics/ethics/review_bodies_guide_serg/en/index.html

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